

AMENDMENTS TO THE SPECIFICATION

On page 22, line 31, following: "(intravascular delivery of plasmid DNA)." --

please insert:

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Figure 3. Western blot detection of luciferase expression in 293 cells using antibodies from serum of genetically immunized mice receiving 3 injections (prime + 2 boosts).

Figure 4. Western blot detection of luciferase expression in 293 cells using antibodies from serum of genetically immunized mice receiving 4 injections (prime + 3 boosts). --

The descriptions are taken from the text in Example 8. The brief descriptions of figures 3 and 4 add no new matter.

Replacement Sheets showing the changes made is included.

In another preferred embodiment we describe a genetic immunization composition formulated for inducing an antigen-specific immune response. A nucleic acid sequence encoding a peptide contains at least one antigenic determinant, operatively linked to one or more control sequences such that the nucleic acid sequence is expressible in a host cell. The 5 nucleic acid sequence is optionally formulated into a particle by complexation with a polymer, for delivery to a vertebrate host cell.

In another preferred embodiment we describe a method for generating an antibody response in a vertebrate host. We administer a nucleic acid encoding an antigen, the nucleic acid optionally being complexed to a polymer, in an amount sufficient to induce the desired 10 immune response directed against the expressed antigen.

In another preferred embodiment we describe a method for generating an immune response in a vertebrate host. We administer a nucleic acid encoding an antigen, the nucleic acid optionally being complexed to a polymer, in an amount sufficient to induce the desired immune response directed against the expressed antigen. The nucleic acid is delivered to the 15 intestinal lumen.

In another preferred embodiment we describe a kit for genetic immunization and detection of a genetic immune response. The kit consists of transfection complexes for *in vivo* and *in vitro* gene transfer.

20 **BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1. Staining of human dystrophin expressing myofibers in *mdx* mice (1:40 serum dilution; FITC-labeled goat-anti-mouse IgG secondary). The mice were injected with a human dystrophin expression vector (CMV promoter) one week before sacrifice. The anti-human dystrophin antibody was generated by genetic immunization in ICR mice (intravascular delivery of plasmid DNA into the tail vein).

Figure 2: Western blotting detection of luciferase antigen generated in cell lines with an antibody raised by genetic immunization. LacZ and Luciferase transfected 293 (left) and Hepa (right) cells were loaded in three concentrations (2, 6, and 10×10^4 cells). Following 30 electrophoresis and blotting, membranes were incubated with a 1:2,000 dilution of serum collected from a pCI-Luc immunized mouse (intravascular delivery of plasmid DNA).

Figure 3. Western blot detection of luciferase expression in 293 cells using antibodies from serum of genetically immunized mice receiving 3 injections (prime + 2 boosts).

35 Figure 4. Western blot detection of luciferase expression in 293 cells using antibodies from serum of genetically immunized mice receiving 4 injections (prime + 3 boosts).

DETAILED DESCRIPTION OF THE INVENTION

I. Definitions

To facilitate an understanding of the present invention, a number of terms and phrases
5 are defined below:

The term “nucleic acid” is a term of art that refers to a polymer containing at least two nucleotides. “Nucleotides” contain a sugar deoxyribose (DNA) or ribose (RNA), a base, and a phosphate group. Nucleotides are the monomeric units of nucleic acid polymers.

Nucleotides are linked together through the phosphate groups to form nucleic acid. A
10 “polynucleotide” is distinguished here from an “oligonucleotide” by containing more than 100 monomeric units; oligonucleotides contain from 2 to 100 nucleotides. “Bases” include purines and pyrimidines, which further include natural compounds adenine, thymine, guanine, cytosine, uracil, inosine, and other natural analogs, and synthetic derivatives of purines and pyrimidines, which include, but are not limited to, modifications which place
15 new reactive groups such as, but not limited to, amines, alcohols, thiols, carboxylates, and alkylhalides. The term nucleic acid includes deoxyribonucleic acid (“DNA”) and ribonucleic acid (“RNA”). The term nucleic acid encompasses sequences that include any of the known base analogs of DNA and RNA including, but not limited to, 4-acetylcytosine, 8-hydroxy-N6-methyladenosine, aziridinylcytosine, pseudouracil, 5-(carboxyhydroxymethyl)
20 uracil, 5-fluorouracil, 5-bromouracil, 5-carboxymethylaminomethyl-2-thiouracil, 5-carboxymethylaminomethyluracil, dihydrouracil, inosine, N6-isopentenyladenine, 1-methyladenine, 1-methylpseudouracil, 1-methylguanine, 1-methylinosine, 2,2-dimethylguanine, 2-methyladenine, 2-methylguanine, 3-methylcytosine, 5-methylcytosine, N6-methyladenine, 7-methylguanine, 5-methylaminomethyluracil, 5-methoxyamino-
25 methyl-2-thiouracil, beta-D-mannosylqueosine, 5'-methoxycarbonylmethyluracil, 5-methoxyuracil, 2-methylthio-N6-isopentenyladenine, uracil-5-oxyacetic acid methylester, uracil-5-oxyacetic acid, oxybutoxosine, pseudouracil, queosine, 2-thiocytosine, 5-methyl-2-thiouracil, 2-thiouracil, 4-thiouracil, 5-methyluracil, N-uracil-5-oxyacetic acid methylester, uracil-5-oxyacetic acid, pseudouracil, queosine, 2-thiocytosine, and 2,6-diaminopurine.

30 Nucleic acids may be linear, circular, or have higher orders of topology (e.g., supercoiled plasmid DNA). DNA may be in the form of anti-sense, plasmid DNA, parts of a plasmid DNA, vectors (P1, PAC, BAC, YAC, artificial chromosomes), expression cassettes, chimeric sequences, chromosomal DNA, or derivatives of these groups. RNA may be in the form of oligonucleotide RNA, tRNA (transfer RNA), snRNA (small nuclear RNA), rRNA (ribosomal RNA), mRNA (messenger RNA), anti-sense RNA, (interfering) double stranded
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